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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,458	10/28/1999	KJETIL TASKEN	Q-56244	4681

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 07/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/428,458

Applicant(s)

TASKEN ET AL.

Examiner

Karen A. Lacourciere

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 40-45, 47-49 and 51.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 03-03-04, 06-10-04.
10. ☒ Other: See Continuation Sheet

  
KAREN A. LACOURCIERE, PH.D  
PRIMARY EXAMINER

Karen A. Lacourciere

Continuation of 3. Applicant's reply has overcome the following rejection(s): Applicant's reply overcomes the objection to the declaration the rejection of record of claims 40-42 under 35 USC 102 under Gjersten et al. because the subject matter disclosed by Gjersten et al. has been canceled, the rejection of record of claims 40-44 under 35 USC 102(e) as anticipated by Cho-Chung et al. because the subject matter disclosed by Cho-Chung et al. has been canceled.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant argues that the rejection of record under 35 USC 112, first paragraph over claims 40-45, 47-49 and 51 should be withdrawn because the Declaration filed June 19, 2002 demonstrate that MAIDS mice exhibit T-cell function in treatment with Rp-8-Br-cAMPS and this supports the utility of the claimed compounds in humans and other animals. This is not found to be persuasive because the amended claims are no longer directed to methods in mice or with the use of Rp-8-Br-cAMPS. Further, the claims are directed to specific diseases that are not represented by the MAIDS mouse model, for example, AIDS in humans. Claim 43, in particular, is directed to a broad scope of methods, none of which are directed to the method of the Declaration of June 19, 2002. The results in this Declaration do not appear to be directed to the specifically claimed methods and do not support their enablement. Applicant argues the in the Office Action mailed May 6, 2003 the prior Examiner acknowledged that the claims were enabled, however, this is not persuasive because the Examiner explicitly states that the claims are no generally enabled for the scope of any treatment method for effects mediated by PKA type I alpha, as claimed by claim 43 and further, the other claimed methods of treatment have been amended since the May 6, 2003 Office action to be narrowed specifically to humans. Although the Examiner may have felt that the broader claims were enabled over a significant scope, narrowing the claims to specifically human excludes the one exemplified in vivo embodiment (both as to the model and the treatment agent used) narrows the methods to a specific scope that is very different than the exemplified embodiment and it does not seem that the Examiner's comments were directed to the methods of treatment now claimed. Applicant further argues that the Declaration filed November 6, 2003 provides data to support the enablement of the claimed methods by demonstrating the enhancement of T-cell proliferation. This is not persuasive because the majority of the data is directed to compounds and models that are specifically excluded from the claims (e.g. mice and Rp-8-cAMPS). The data does not address the very broad scope of methods claimed in claim 43 (e.g. PKA R1a effects unrelated to T-cells). Applicant argues that although Gjertsen et al. demonstrate that all compounds of the class do not work equally well, the data in Gjersten et al. is not clearly supportive of the unpredictability of the antagonist properties because Gjersten et al. is only concerned with finding the most potent compounds and does not rule out that other compounds of the class are not antagonists, but less potent. This has not been found to be persuasive because although other compounds may act as less potent antagonists, it is unpredictable that the level of antagonism is effective to provide a degree of inhibition that would be sufficient to produce the effects of treating a disease, as required by the claimed methods. Applicant argues that the experimentation to practice the claimed methods would be routine, however, given the unpredictability of the methods, and the nature of the diseases being treated and the broad scope of the claims (particularly claim 43), this experimentation would be undue, as discussed in the rejection of record. Screening for the activity of these compounds may be routine, however, the methods are directed at methods of treatment for a range of specific diseases, which is not routine and would require undue experimentation beyond Gjersten's screening method. Even through the routine experimentation is unpredictable that the treatment effects required by the claims would be achieved.

Continuation of 10. Other: The IDS filed 03-03-04 has been considered. The IDS filed 06-10-2004 has not been considered because it does not meet the requirements set forth in 37 CFR 1.97, specifically, it is more than 3 months past the receipt of a communication listing the documents from a foreign patent office and it is not accompanied by the required statement.